

REMARKS

The Examiner rejected claim 36 under 35 USC 112, second paragraph, claims 33-36, 38 and 41 under 35 USC 103(a) as being unpatentable over Davis-Lemessy et al. (6,139,525), and claims 39 and 40 under 35 USC 103(a) as being unpatentable over Davis-Lemessy et al. in view of Okuda et al. (6,053,939), stating that the indicated allowability of the claims is withdrawn in view of the newly discovered reference to Lim et al. Claims 33-36 and 38-41 are pending.

Regarding the rejection of claim 36 under 35 USC 112, second paragraph, the Examiner requires appropriate amendment or clarification of whether the adhesive is the plasma-polymerized film. Applicants have amended claim 36 to clarify that the adhesive is not the plasma-polymerized film.

Regarding the rejection of claims 33-36, 38 and 41 under 35 USC 103(a) as being unpatentable over Davis-Lemessy et al., and claims 39 and 40 as being unpatentable over Davis-Lemessy et al. in view of Okuda et al., the Examiner states, in part, that Davis-Lemessy et al. discloses a balloon catheter having a fusion bond containing a compatibilizing material, and that the compatibilizing agent may be used alone or in combination with a surface treatment of one or both opposed surfaces, the surface treatment consisting of a plasma treatment applied to either the surface of the balloon, the surface of the shaft, or both, and the surface treatment acts by providing functional groups and increasing surface area which facilitates fusion bond formation between the compatibilizing agent and the shaft and balloon, and that that preferred compatibilizing agent is ethylene acrylic ester and an ethylene acrylic acid copolymer, and that although

Davis-Lemessy et al. does not teach that the acrylic layer of the compatibilizing agent is 10-150 nm in thickness, it would have been obvious to optimize the thickness of the compatibilizing layer as taught by Davis-Lemessy et al. given that the thickness of a coating can be controlled to obtain specific properties and it is desirable to obtain a thin coating thickness for a bonding layer.

However, Davis-Lemessy et al. discloses that irrespective of the method used to apply the compatibilizer layer, the compatibilizing agent thickness should range from about 0.5 mm to about 4.0 mm (see col. 5, lines 41-45). Therefore, contrary to the Examiner's assertion, it would not have been obvious to modify Davis-Lemessy to provide the compatibilizing layer with a thickness at least 3 orders of magnitude smaller than the thickness which Davis-Lemessy states should be used (i.e., Applicant's 150 nm thickness film vs. Davis-Lemessy's 500,000 nm (0.5 mm) thickness compatibilizer). In contrast to Applicant's invention of claim 33 requiring a thin plasma-polymerized film covalently bound to the first layer, Davis-Lemessy discloses the use of a compatibilizing agent, preferably a hot melt adhesive, which fusion bonds to both the material of the balloon and the material of the shaft. The hot melt adhesive compatibilizing agent is therefore applied as a relatively thick layer between the balloon and shaft, unlike the relatively thin film required by Applicant's claims. The compatibilizing agents referred to by the Examiner (ethylene acrylic ester maleic anhydride and an ethylene acrylic acid copolymer) are polyethylene based adhesives. As discussed in Applicant's specification at paragraph [0004], relying solely on adhesives is not ideal for flexibility or bond strength.

The Examiner further states that Davis-Lemessy et al. discloses that the compatibilizing agent may be used alone or in combination with a surface treatment of one or both opposed surfaces, the surface treatment consisting of a plasma treatment applied to either the surface of the balloon, the surface of the shaft, or both, and the surface treatment acts by providing functional groups and increasing surface area which facilitates fusion bond formation between the compatibilizing agent and the shaft and balloon. However, the specific surface treatments disclosed by Davis-Lemessy et al. are cleaning treatments (i.e., Argon plasma, or solvents) wherein any modification/functionalization which results therefrom does not result in a thin plasma polymerized acrylate or fragmented acrylate polymer film covalently bonded to the surface of the catheter component. In fact, Applicant's similarly disclose that "[t]he section may be first treated with an argon plasma to prepare the surface prior to exposure to the plasma polymerized film deposition", "to remove organic processing debris from the surface of the ePTFE film before deposition of the plasma polymerized film" (see paragraphs [0011] and [0023]).

The Examiner states that determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. However, the requirement in Applicant's claim 33 of a 10-150 nm thickness acrylate or fragmented acrylate polymer film covalently bonded to at least a section of a first surface of the first layer is a structural limitation not disclosed or suggested by Davis-Lemessy. As discussed in Applicant's specification, the plasma polymerized film results in a permanent (stable) surface modification, with the covalently bonded film providing


for improved, advantageous, strong bonding of catheter components. Davis-Lemessy, directed to use of hot melt adhesives to bond polymeric materials (e.g., incompatible polymeric materials such as nylon and high density polyethylene), does not disclose or suggest such a configuration. Copolymers with acrylic acid functional groups are a large chemical family. Although Davis-Lemessy discloses a catheter having an adhesive which includes acrylic functional groups, such disclosure does not render obvious Applicant's invention directed to a plasma polymerized film as set forth above.

Applicants filed an Information Disclosure Statement with the Amendment of 05 October 2005. Applicants have received from the Examiner a signed copy of the FORM PTO-1449 filed with the Information Disclosure Statement, but the Examiner appears to have inadvertently neglected to initial the citation on the signed copy. Applicants hereby request a copy of the FORM PTO-1449, filed 05 October 2005, initialed by the Examiner to indicate consideration of the reference listed thereon.

In light of the above amendments and remarks, applicant respectfully requests reconsideration and that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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